REMARKS

I. Introduction

With the addition of new claim 44, claims 11, 12, 15 to 20, 28, 31 to 33, 39, 40, and 42 to 44 are pending in the present application. In view of the foregoing amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable, and reconsideration is respectfully requested.

II. Rejection of Claim 20 Under 35 U.S.C. § 112, Second Paragraph

Claim 20 was rejected under 35 U.S.C. § 112, second paragraph as indefinite. Applicants respectfully submit that 20 fully complies with 35 U.S.C. § 112, second paragraph, which merely requires that a claim set out and circumscribes a particular subject matter with a reasonable degree of clarity and particularity. Accordingly, withdrawal of this rejection is respectfully requested.

III. Rejection of Claims 11, 12, 15 to 17, 28, 31 to 33, and 39 to 43 Under 35 U.S.C. § 102(b)

Claims 11, 12, 15 to 17, 28, 31 to 33, and 39 to 43 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,176,127 ("Dormia"). It is respectfully submitted that Dormia does not anticipate these claims for at least the following reasons.

Claim 11 relates to an orifice introducer device. As amended herein without prejudice, claim 11 recites that the device includes: a tubular member having a lumen and a distal end; a distal portion having a proximal end detachably connected to the tubular member, the proximal end having an annular groove that receives the distal end of the tubular member <u>such that the distal end of the</u> <u>tubular member contacts a side of the annular groove to constrain the</u> <u>proximal end of the distal portion against radial contraction</u>, wherein, when the distal portion is detached from the distal end of the tubular member, the proximal end of the distal portion contracts to have a smaller diameter than a diameter of the tubular member. Support for this amendment may be found, for example, at page 10, lines 11 to 28 of the Specification.

Claim 28 relates to a method for using an orifice introducer device. As amended herein without prejudice, claim 28 recites that the method includes:

providing a tubular member having a distal end; detachably securing a proximal end of a distal portion to the distal end of the tubular member by receiving the distal end of the tubular member in an annular groove at the proximal end of the distal portion such that the distal end of the tubular member contacts a side of the annular groove to constrain the proximal end of the distal portion against radial contraction, a distal end of the distal portion having a smaller diameter than the tubular member; inserting the distal end of the distal portion into an orifice; selectively detaching the distal portion from the tubular member; the distal portion contracting so as to have a diameter smaller than a diameter of the tubular member; and withdrawing the distal portion through the tubular member. Support for this amendment may be found, for example, at page 10, lines 11 to 28 of the Specification.

Claim 39 relates to a device. Claim 39 recites that the device includes: a tubular member having a distal end, the tubular member having therein a surgical stapler apparatus; a second member being arranged internally within the tubular member and being configured to move longitudinally relative to the tubular member; and a distal portion having a proximal end mounted to the distal end of the tubular member, the proximal end having an annular groove that receives the distal end of the tubular member <u>such that the distal end of the tubular member contacts a side of the annular groove to constrain the proximal end of the distal portion against radial contraction</u>, the distal portion being selectively detachable from the tubular member by engagement with the second member when the second member is moved distally longitudinally. Support for this amendment may be found, for example, at page 10, lines 11 to 28 of the Specification.

Dormia relates to a mandrel for a medical endoscope and describes a mandrel head 9 that expands to extend over the end 3 of the jacket 1. See, e.g., col. 3, lines 58 to 63, col. 4, lines 3 to 50 and Figures 3 and 8. In this regard, the mandrel head 9 is held in the expanded state by using rod-shaped slide or mandrel 10, the mandrel head moving radially inwardly when the mandrel 10 is removed. Col. 4, lines 3 to 60 and Figures 6 and 8.

The Final Office Action contends at page 3 that element 18 in Figure 8 of Dormia constitutes an annular groove. The Final Office Action further contends that element 1 of Dormia constitutes a tubular member. However, no side of element 18 is contacted by element 1 in any manner that constrains a proximal end

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of the mandrel head 9, which the Final Office Action considers to constitute a distal portion, against radial contraction. Rather, as indicated above, any expansion and contraction of the mandrel head 9 is dictated by the insertion and removal of the mandrel 10. Thus, it is plainly apparent that Dormia does disclose, or even suggest, a distal portion including a proximal end having an annular groove that receives the distal end of a tubular member <u>such that the distal end of the tubular member</u> <u>contacts a side of the annular groove to constrain the proximal end of the distal portion against radial contraction</u>, as recited in claims 11 and 39, or the step of detachably securing a proximal end of a distal portion to a distal end of a tubular member by receiving the distal end of the tubular member in an annular groove at the proximal end of the distal portion <u>such that the distal end of the tubular member contacts a side of the annular groove to constrain the proximal end of the distal portion against radial contraction</u>, as recited in claim 28.

As indicated above, Dormia does not disclose, or even suggest, all of the features recited in any of claims 11, 28, and 39. As such, it is respectfully submitted that Dormia does not anticipate any of claims 11, 28, and 39, or any claim that depends from any of claims 11, 28, and 39. Accordingly, withdrawal of this rejection is respectfully requested.

IV. Rejection of Claims 11 and 12 Under 35 U.S.C. § 102(b)

Claims 11 and 12 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,931,776 ("Dotolo"). It is respectfully submitted that Dotolo does not render unpatentable these claims for at least the following reasons.

As set forth above, amended claim 11 recites: a tubular member having a lumen and a distal end; a distal portion having a proximal end detachably connected to the tubular member, the proximal end having an annular groove that receives the distal end of the tubular member <u>such that the distal end of the</u> <u>tubular member contacts a side of the annular groove to constrain the</u> <u>proximal end of the distal portion against radial contraction</u>, wherein, when the distal portion is detached from the distal end of the tubular member, the proximal end of the distal portion contracts to have a smaller diameter than a diameter of the tubular member.

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Dotolo relates to a speculum 10 having a dissolvable tip 12. After insertion, the tip 10 is purportedly dissolved by "transient water flowing through the speculum 10." Col. 2, lines 63 to 65.

Referring to Figures 1 and 2, the Final Office Action contends that portion 16 of the dissolvable tip 12 constitutes an annular groove of a distal portion and the dissolving of the tip constitutes contraction. The Final Office Action further contends that speculum 10 constitutes a tubular member. However, it is plainly apparent that the end of the speculum 10 does not contact a side of portion 16 to constrain the tip 12 against radial contraction. Thus, it is plainly apparent that Dotolo does disclose, or even suggest, a distal portion including a proximal end having an annular groove that receives the distal end of a tubular member <u>such that the distal</u> end of the tubular member contacts a side of the annular groove to constrain the proximal end of the distal portion against radial contraction, as recited in claim 11.

As indicated above, Dotolo does not disclose, or even suggest, all of the features recited in claim 11. As such, it is respectfully submitted that Dotolo does not anticipate claim 11 or claim 12, which depends from claim 11. Accordingly, withdrawal of this rejection is respectfully requested.

V. Rejection of Claims 20 and 39 to 43 Under 35 U.S.C. § 103(a)

Claims 20 and 39 to 43 were rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Dormia and U.S. Patent No. 6,042,538 ("Puskas"). It is respectfully submitted that the combination of Dormia and Puskas does not render unpatentable these claims for at least the following reasons.

As an initial matter, claim 41 has been previously canceled. As such, the present rejection of claim 41 is moot.

Claim 20 depends from claim 11 and therefore includes all of the features of claim 11. As indicated above, Dormia does not disclose, or even suggest, all of the features of claim 11. Puskas is not relied upon for disclosing the features of claim 11 not disclosed or suggested by Dormia. Indeed, Puskas does not disclose, or even suggest, the features of claim 11 not disclosed or suggested by Dormia. As such, the combination of Dormia and Puskas et al. does not disclose, or even suggest, all of the features of claim 20. Accordingly, it is respectfully submitted that the combination of Dormia and Puskas does not render unpatentable claim 20.

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As indicated above, Dormia does not disclose, or even suggest, all of the features of claim 39. Puskas is not relied upon for disclosing the features of claim 39 not disclosed or suggested by Dormia. Indeed, Puskas does not disclose, or even suggest, the features of claim 39 not disclosed or suggested by the by Dormia. As such, it is respectfully submitted that the combination of Dormia and Puskas does not render unpatentable claim 39 or any of claims 40, 42, and 43, which depend from claim 39.

In view of all of the foregoing, withdrawal of this rejection is respectfully requested.

VI. Rejection of Claims 18 and 19 Under 35 U.S.C. § 103(a)

Claims 18 and 19 were rejected under 35 U.S.C. § 103(a) as unpatentable over Dormia. It is respectfully submitted that Dormia does not render unpatentable these claims for at least the following reasons.

Claims 18 and 19 ultimately depend from claim 11 and therefore include all of the features of claim 11. As set forth above, Dormia does not disclose, or even suggest, all of the features of claim 11. Accordingly, Dormia does not disclose, or even suggest, all of the features of either of claims 18 and 19. As such, Dormia does not render unpatentable either of claims 18 and 19. Withdrawal of this rejection is therefore respectfully requested.

VII. New Claim 44

New Claim 44 has been added. It is respectfully submitted that new claim 44 adds no new matter and is fully supported by the present application, including the Specification. Claim 44 recites features similar to those recited in claims 11 and 39. As such, it is respectfully submitted that claim 44 is allowable over the cited references for at least the same reasons set forth above.

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VIII. Conclusion

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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